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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/663,238	09/16/2003	Alain V. Khaiat	J&J5037CIP1	3755	
27777	7590 05/25/2006		EXAMINER		
PHILIP S. JO		ŲU, JAKE MINH			
JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA			ART UNIT	PAPER NUMBER	
• · · · · · · · · · · · · · · · · · · ·	NEW BRUNSWICK, NJ 08933-7003			1618	
			DATE MAILED: 05/25/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
	10/663,238	KHAIAT ET AL.			
Office Action Summary	Examiner	Art Unit			
	Jake M. Vu	1618			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
 Responsive to communication(s) filed on <u>20 March 2006</u>. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. 					
Disposition of Claims					
4) Claim(s) 1-4,6-12 and 14-27 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-4, 6-12 and 14-27 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 					
Priority under 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 					
Attachment(s)					
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed 03/20/06. Claims 1, 2, 6, 7, 12, 14, 20, 21, 25 and 27 have been amended. Claims 5 and 13 have been cancelled. Claims 1-4, 6-12 and 14-27 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 9, 11 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by WALDSTRICHER (US 5,543,417).

Applicant's claims are directed to a method of use and composition comprising of: a 5-alpha-reductase inhibitor; an anti-inflammatory agent, such as allantoin; a keratolytic agent, such as salicylic acid; and a bacterial proliferation inhibitor, such as clindamycin.

WALDSTREICHER disclosed a method of treating acne by applying a composition comprised of: 5-alpha-reductase inhibitor (abstract); an anti-inflammatory agent, such as allantoin (abstract and col. 63, line 56); a keratolytic agent, such as salicylic acid (col. 59, line 12); and a bacterial proliferation inhibitor, such as clindamycin (col. 58, line 59).

Art Unit: 1618

Note, the capable of limitation "whereby the appearance of said skin improves within two days of said topical application" is inherent, since the prior art's composition has the same ingredients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 6, 7, 9-11, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WALDSTREICHER (US 5,543,417) in view of DALKO et al (US 6,846,812), and CHAN et al (The analgesic and anti-inflammatory effects of Portulaca oleracea L. subsp. Sativa (Haw.) Celak. J Ethnopharmacol. 2000 Dec; 73(3):445-51).

Applicant's claims are directed to a method of use and composition comprising of: 5-alpha-reductase inhibitors, such as a glycine; anti-bacterial agents such as clindamycin; keratolytic agents, such as salicylic acid; and anti-inflammatory agents, such as portulaca extract.

WALDSTREICHER disclosed an acne treating composition comprised of: 5-alpha-reductase inhibitors; anti-bacterial agents, such as clindamycin (col. 58, line 59); keratolytic agents, such as salicylic acid (col. 59, line 12); and anti-inflammatory agents.

Application/Control Number: 10/663,238

Art Unit: 1618

WALDSTREICHER does not specifically teach using 5-alpha-reductase inhibitors, such as a glycine or anti-inflammatory agents, such as portulaca extract.

DALKO disclosed a 5-alpha-reductase inhibitor, such as capryloyl glycine, which is a glycine, and cinnamon extract for treating seborrhea and acne (col. 8, line 53-55 and col. 9, line 9-11).

CHAN disclosed an anti-inflammatory agent, such as portulaca extract, which possessed significant anti-inflammatory activities when compared with synthetic drugs (abstract and pg. 446).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate capryloyl glycine, cinnamon extract, and portulaca extracts into WALDSTRICHER's composition. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because these ingredients are the same type of ingredients used by WALDSTRICHER.

Claims 1-4, 6-12 and 14-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over WALDSTREICHER (US 5,543,417) in view of DALKO et al (US 6,846,812), CHAN et al (The analgesic and anti-inflammatory effects of Portulaca oleracea L. subsp. Sativa (Haw.) Celak. J Ethnopharmacol. 2000 Dec; 73(3):445-51), and SATO et al (US 5,200,429).

As discussed above, WALDSTREICHER disclosed an acne treating composition comprised of: 5-alpha-reductase inhibitors; anti-bacterial agents, such as clindamycin

Application/Control Number: 10/663,238

Art Unit: 1618

(col. 58, line 59); keratolytic agents, such as salicylic acid (col. 59, line 12); and anti-inflammatory agents. DALKO disclosed a 5-alpha-reductase inhibitor, such as capryloyl glycine, which is a glycine, and cinnamon extract for treating seborrhea and acne (col. 8, line 53-55 and col. 9, line 9-11). CHAN disclosed an anti-inflammatory agent, such as portulaca extract, which possessed significant anti-inflammatory activities when compared with synthetic drugs (abstract and pg. 446).

These references do not teach using a bacterial lipase inhibitor such as cedarwood extract.

SATO disclosed using cedarwood extracts for treating acne (col. 2, line 54 and abstract).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients for treating acne. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. In this instance, Applicant's composition is used for treating acne. The idea for combining them flows logically from their having been used individually in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072. MPEP § 2144.06 Art Recognized Equivalence for the Same Purpose.

Based on the disclosure by these references that these substances are used to treat acnes, an artisan of ordinary skill would have a reasonable expectation that a combination of the ingredients would also be useful in creating compositions to treat acnes. Therefore, the artisan would have been motivated to combine the claimed

Application/Control Number: 10/663,238

Art Unit: 1618

ingredients into a single composition. No patentable invention resides in combining old

ingredients of known properties where the results obtained thereby are no more that the

additive effect of the ingredients. See In re Sussman, 1943 C.D. 518; In re Huellmantel

139 USPQ 496; In re Crockett 126 USPQ 186.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in

this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Application/Control Number: 10/663,238 Page 7

Art Unit: 1618

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148.

The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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Business Center (EBC) at 866-217-9197 (toll-free).

Jake M. Vu, PharmD, JD

Art Unit 1618

SUPERVISORY PATENT EXAMINER